

In re Application of: Lola WEISS et al  
Serial No.: 10/589,623  
Filed: August 16, 2006  
Office Action Mailing Date: February 22, 2011

Examiner: Jennifer M. KIM  
Group Art Unit: 1628  
Attorney Docket: **32361**  
Confirmation No.: 3826

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-5, 8-10 and 24 and 26 are in this Application. Claims 19-23 have been withdrawn from consideration. Claims 1-5 and 8-10 have been rejected under 35 U.S.C. § 112. Claims 1-5, 8-10 and 26 have been rejected under 35 U.S.C. § 102. Claims 1-5, 8-10, 24 and 26 have been rejected under 35 U.S.C. § 103. Claims 2-3 and 26 have been canceled herewith. Claims 1 and 4 have been amended herewith.

### **Amendments To The Claims**

#### **35 U.S.C. § 112 Rejections**

The Examiner rejected claims 1-5 and 8-10 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling for prevention of diabetes.

Examiner's rejection is respectfully traversed. Applicants would like to note that clearly as evidenced by the instant specification, the claimed treatment prevents progression of the disease since it prolongs beta cell survival. Notwithstanding the above, and in order to expedite prosecution, Claim1 has been amended to remove the term "preventing".

The Examiner has further rejected claims 2 and 3 under 35 U.S.C. § 112, Second paragraph for extending beyond the scope of claim 1 from which they depend.

While traversing the rejection, please claims 2-3 have been cancelled herewith, thereby rendering the rejection moot.

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35 U.S.C. § 102 Rejections

The Examiner rejected claims 1-5 and 8-10 and 26 under 35 U.S.C. § 102 as being anticipated by R&D Profile record (2003).

The Examiner rejected claims 1-5 and 8-10 and 26 under 35 U.S.C. § 102 as being anticipated by Hampson et al. (WO 99/53917).

The Examiner has indicated that removal of the term "preventing" would render the claims free of the above art.

While traversing the rejection and in order to expedite prosecution, claim 1 has been amended to remove the term "preventing" thereby rendering the rejection moot. Applicants would like to note that clearly as evidenced by the instant specification, the claimed treatment prevents progression of the disease since it prolongs beta cell survival.

For the above amendment and arguments, withdrawal of the rejection is requested.

35 U.S.C. § 103 Rejections

The Examiner has rejected claims 1-5, 8-10, 24 and 26 under 35 U.S.C 103, as being unpatentable over R&D Profile of record (2003) in view of Spevak (7,071,231) and Gorter (1999).

The Examiner specifically states that R&D profile teaches the D9 THC and CBD have been employed in a clinical trial of peripheral neuropathy secondary to diabetes mellitus. Spevak et al. teach that Type II is the most prevalent form of diabetes and Gorter teaches that CBD antagonizes the psychotropic actions of THS. Therefore the skilled in the art would use the composition described in the R&D profile for the treatment of T2DM given the excellent safety data and the absence of psychotropic activity as taught by Gorter.

The rejection is traversed.

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Attached is a Declaration by co-inventor Ruth Gallily under 37 CFR 1.132 attesting to the fact that the composition taught in the R&D profile publication (describing GW's R&D) possesses psychotropic activity.

For this reason, GW's composition can't be used to anticipate the claimed invention even when combined with the art of Gorter, since at the end of the day the GW composition described in the R&D profile and further in the product's SPC is endowed with psychotropic activity.

Claim 26 has now been cancelled and claim 1 amended. No new matter has been added.

### **Conclusion**

In view of the above amendments and remarks it is respectfully submitted that claims 1, 4, 5 and 8-10 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Date: July 19, 2011

### **Enclosures:**

- Petition for Extension (Two Months)
- Declaration and CV of Inventor Ruth GALLILY
- Ruth GALLILY last publications
- Reference: Summary of Product Characteristics